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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/110,376 05/12/98 COHEN

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EXAMINER

HM12/0323

THE LAW OFFICE OF JAMES C SIMMONS  
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WILLIAMSVILLE NY 14221

EYLER, Y

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

03/23/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

# Office Action Summary

Application No.

09/110,376

Applicant(s)

Cohen et al.

Examiner

Yvonne Eyler

Group Art Unit

1642



☒ Responsive to communication(s) filed on Jan 14, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) 2-5 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election without traverse of Group I, claim 1 in Paper No. 9 is acknowledged. Claims 2-5 are withdrawn from further consideration as being drawn to a non-elected invention.

### ***Priority***

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

The instantly claimed invention is drawn to a method of predicting metastatic potential of solid, non-lymphoid tumors by detection of expressed lymphoid gene products within the tumor cells. This invention was not disclosed or contemplated in the parent applications, serial nos. 08/680,372 or 08/118,969. The parent applications disclose and contemplate prediction of metastatic behavior by detection of a single lymphoid gene product, IL-2R. Further detection of TCR is contemplated to be useful in monitoring chemotherapy but is not correlated or suggested

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to be predictive of metastatic potential. On the contrary, TCR expression is taught, in the parent applications, to be generally associated with tumor cells. Thus, the instantly claimed invention receives a priority date, for art purposes, of the instant filing date of 05/12/98.

***Specification***

The disclosure is objected to because of the following informalities:

The Brief Description of the Figures fails to describe Figures 22a and 22b separately.

The continuing data on the first line of the specification should be updated to indicate that U.S. serial number 08/680372 is now abandoned.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "lymphoid gene products" is vague and indefinite because the metes and bounds cannot be determined. The specification on page 2 gives examples of various products which are included by the phrase, but does not provide a clear, descriptive, definitive definition such that the unambiguous identification of whether a product is or is not encompassed may be accomplished.

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### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,536,642 (IDS-J).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed method of '642 is a species and is encompassed by the instant method of predicting lymphotropic metastatic potential by detection of expression of lymphoid gene products, such as IL-2R.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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7. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Barbera-Guillem et al. (U.S.# 5,536,642).

Barbera-Guillem et al teach a method of determining the probability of metastasis by detecting the level of expression of the lymphoid gene product, IL-2R, thus meeting the instant claim limitations. See the abstract, and column 2, lines 55-60.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. (Int. J. Oncology 3:368-373, 1993-IDS 23) or Kim et al. (Proc. Am. Assoc. Cancer Res. 34:62, 1993-IDS 43).

Mayer et al. teach that detection of the lymphoid gene product, *lck* transcripts was known to be a marker for metastasis of epithelial tumor cells. Mayer et al. further teach that progression of colorectal cancer cells to a metastatic stage was known to be accompanied by expression of lymphocyte-specific genes. See pages 368, column 1; and page 371, column 1.

Kim et al. teach the association between metastatic potential and expression of several lymphoid gene products.

It would have been *prima facie* obvious to one of ordinary skill in the art to detect lymphoid gene product expression within solid, non-lymphoid tumor cells to predict metastatic potential with a reasonable expectation of success given the correlations between metastasis and lymphoid gene expression taught by Mayer et al. or Kim et al. and their recognized status as metastatic markers.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yvonne Eyler, Ph.D. whose telephone number is (703) 308-6564. The examiner can normally be reached on Monday through Friday from 830am to 630pm.

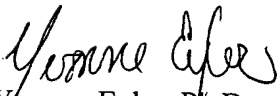
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [paula.hutzell@uspto.gov].

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All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Yvonne Eyler, Ph.D.  
Primary Examiner  
March 22, 2000